

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joerg Schneider, Sarah C. Gilbert, Carolyn M. Hannan and Adrian V.S. Hill
Application No.: 10/088,677 Group Art Unit: 1645
371(c) Date: May 31, 2002 Examiner: Robert A. Zeman
Confirmation No.: 4825
Title: USE OF REPLICATION-DEFICIENT ADENOVIRAL VECTOR TO BOOST
CD8+T CELL IMMUNE RESPONSE TO ANTIGEN

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
September 15, 2006	<i>Marianne Lentini</i>
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Typed or printed name of person signing certificate	

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Third Supplemental Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.
(Filed after payment of issue fee)

09/20/2006 RHEBRAHT 00000001 10088677 180.00 OP
01 FC:1806

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references, B6-B11 and C32-C145, are enclosed.
 - ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☒ The "concise explanation" requirement (non-English references) for references B10, B11 and C95 under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☒ the enclosed English language abstracts.

- ☐ Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.


Method of payment:

- ☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

September 15, 2006

APPLICATION NO.
10/088,677

371(C) DATE
May 31, 2002

CONFIRMATION NO.
4825

GROUP
1645

September 15, 2006

(Use several sheets if necessary)

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DATE CONSIDERED

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	FIRST NAMED INVENTOR Joerg Schneider		371(C) DATE May 31, 2002	
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION	
					YES	NO
	B6	WO 93/03145	02-18-1993	Virogenetics Corporation		
	B7	WO 96/26271 A1	08-29-1996	Therion Biologics Corporation and The United States Government, represented by The Department of Health and Human Services		
	B8	WO 98/04728 A1	02-05-1998	Therion Biologics Corporation and United States Government, as represented by The Department of Health and Human Services		
	B9	WO 01/85932 A2	11-15-2001	Aventis Pasteur Limited and Ludwig Institute for Cancer Research		
	B10	WO 02/068654 A2	09-06-2002	Centro de Ingenieria Genetica y Biotecnologia		X
	B11	EP 0 517 292 B1	02-02-2000	Dimminaco AG		X

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C32	Ada, G., "Do Cytotoxic T Lymphocytes Clear Some HIV/SIV Infections?," <i>J. Med. Primatol.</i> 25(3):158-162 (1996).	
C33	Afonso, C.L., <i>et al.</i> , "The Genome of Fowlpox Virus," <i>J. Virol.</i> 74(8):3815-3831 (2000).	
C34	Aidoo, M., <i>et al.</i> , "Recombinant Vaccinia Viruses for the Characterization of <i>Plasmodium falciparum</i> -specific Cytotoxic T Lymphocytes: Recognition of Processed Antigen Despite Limited Re-Stimulation Efficacy," <i>Intl. Immunol.</i> 9(5):731-737 (1997).	
C35	Aidoo, M., <i>et al.</i> , "Identification of Conserved Antigenic Components for a Cytotoxic T Lymphocyte-inducing Vaccine Against Malaria," <i>Lancet</i> 345(8956):1003-1007 (1995).	
C36	Allsopp, C.E.M., <i>et al.</i> , "Comparison of Numerous Delivery Systems for the Induction of Cytotoxic T Lymphocytes by Immunization," <i>Eur. J. Immunol.</i> 26:1951-1959 (1996).	
C37	Blanchard, T.J., <i>et al.</i> , "Modified Vaccinia Virus Ankara Undergoes Limited Replication in Human Cells and Lacks Several Immunomodulatory Proteins: Implications for Use as a Human Vaccine," <i>J. Gen. Virol.</i> 79:1159-1167 (1998).	
C38	Blanchard, T., <i>et al.</i> , "Future Vaccines for HIV," <i>Lancet</i> 348(9043):1741 (1996).	
C39	Boulanger, D., <i>et al.</i> , "Morphogenesis and Release of Fowlpox Virus," <i>J. Gen. Virol.</i> 81:675-687 (2000).	
C40	Boulanger, D., <i>et al.</i> , "The 131-Amino-Acid Repeat Region of the Essential 39-Kilodalton Core Protein of Fowlpox Virus FP9, Equivariant to Vaccinia Virus A4L Protein, Is Nonessential and Highly Immunogenic," <i>J. Virol</i> 72(1):170-179 (1998).	
C41	Boursnell, M.E.G., <i>et al.</i> , "A Fowlpox Virus Vaccine Vector with Insertion Sites in the Terminal Repeats: Demonstration of its Efficacy Using the Fusion Gene of Newcastle Disease Virus," <i>Vet. Microbiol.</i> 23:305-316 (1990).	
C42	Boursnell, M.E.G., <i>et al.</i> , "Insertion of the Fusion Gene from Newcastle Disease Virus into a Non-essential Region in the Terminal Repeats of Fowlpox Virus and Demonstration of Protective Immunity Induced by the Recombinant," <i>J. Gen. Virol.</i> 71:621-628 (1990).	

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C43	Boyle, D.B. and Heine, H.G., "Recombinant Fowlpox Virus Vaccines for Poultry," <i>Immunol. Cell Biol.</i> 71:391-397 (1993).	
C44	Boyle, D.B., <i>et al.</i> , "Comparison of Field and Vaccine Strains of Australian Fowlpox Viruses," <i>Arch. Virol.</i> 142:737-748 (1997).	
C45	Brooks, J.V., <i>et al.</i> , "Boosting Vaccine for Tuberculosis," <i>Infect. Immun.</i> 69(4): 2714-2717 (2001).	
C46	Brossart, P., <i>et al.</i> , "Virus-Mediated Delivery of Antigenic Epitopes into Dendritic Cells as a Means to Induce CTL," <i>J. Immunol.</i> 158:3270-3276 (1997).	
C47	Campbell, J.I.A., <i>et al.</i> , "Tandem Repeated Sequences within the Terminal Region of the Fowlpox Virus Genome," <i>J. Gen. Virol.</i> 70:145-154 (1989).	
C48	Carroll, M.W., <i>et al.</i> , "Highly Attenuated Modified Vaccinia Virus Ankara (MVA) as an Effective Recombinant Vector: A Murine Tumor Model," <i>Vaccine</i> 15(4):387-394 (1997).	
C49	Carter, B.J., <i>et al.</i> , "Gene Therapy as Drug Development," <i>Mol. Therapy</i> 1(3):211-212 (2000).	
C50	Carvalho, L.J.M., <i>et al.</i> , "Malaria Vaccine: Candidate Antigens, Mechanisms, Constraints and Prospects," <i>Scand. J. Immunol.</i> 56:327-343 (2002).	
C51	Castelli, C., <i>et al.</i> "Mass Spectrometric Identification of a Naturally Processed Melanoma Peptide Recognized by CD8 ⁺ Cytotoxic T Lymphocytes," <i>J. Exp. Med.</i> 181:363-368 (1995).	
C52	Conry, R.M., <i>et al.</i> , "Safety and Immunogenicity of a DNA Vaccine Encoding Carcinoembryonic Antigen and Hepatitis B Surface Antigen in Colorectal Carcinoma Patients," <i>Clin. Cancer Res.</i> 8:2782-2787 (2002).	
C53	Coupar, B.E.H., <i>et al.</i> , "Restriction Endonuclease Mapping of the Fowlpox Virus Genome," <i>Virology</i> 179:159-167 (1990).	
C54	Dale, C.J., <i>et al.</i> , "Induction of HIV-1-Specific T-Helper Responses and Type 1 Cytokine Secretion Following Therapeutic Vaccination of Macaques with a Recombinant Fowlpoxvirus Co-expressing Interferon-Gamma," <i>J. Med. Primatol.</i> 29:240-247 (2000).	

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C55	Davis, H.L., <i>et al.</i> , "DNA-Mediated Immunization to Hepatitis B Surface Antigen: Longevity of Primary Response and Effect of Boost," <i>Vaccine</i> 14(9):910-915 (1996).
C56	Denis, O., <i>et al.</i> , "Vaccination with Plasmid DNA Encoding Mycobacterial Antigen 85A Stimulates a CD4+ and CD8+ T-Cell Epitopic Repertoire Broader than that Stimulated by <i>Mycobacterium tuberculosis</i> H37Rv Infection," <i>Infect. Immun.</i> 66(4):1527-1533 (1998).
C57	Doolan, D.L., <i>et al.</i> , "Circumventing Genetic Restriction of Protection against Malaria with Multigene DNA Immunization: CD8 ⁺ T Cell-, Interferon γ -, and Nitric Oxide-Dependent Immunity," <i>J. Exp. Med.</i> 183(4):1739-1746 (1996).
C58	Doolan, D.L. and Hoffman, S.L., "The Complexity of Protective Immunity Against Liver-Stage Malaria," <i>J. Immunol.</i> 165(3):1453-1462 (2000).
C59	Drexler, I., <i>et al.</i> , "Highly Attenuated Modified Vaccinia Virus Ankara Replicates in Baby Hamster Kidney Cells, a Potential Host for Virus Propagation, but not in Various Human Transformed and Primary Cells," <i>J. Gen. Virol.</i> 79:347-352 (1998).
C60	Egan, M.A., <i>et al.</i> , "Induction of Human Immunodeficiency Virus Type 1 (HIV-1)-Specific Cytolytic T Lymphocyte Responses in Seronegative Adults by a Nonreplicating, Host-Range-Restricted Canaripox Vector (ALVAC) Carrying the HIV-1 _{MN} env Gene," <i>J. Infect. Dis.</i> 171:1623-1627 (1995).
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C63	Fuller, D.H., <i>et al.</i> , "Gene Gun-Based Nucleic Acid Immunization Alone or in Combination with Recombinant Vaccinia Vectors Suppresses Virus Burden in Rhesus Macaques Challenged with a Heterologous SIV," <i>Immunol. Cell Biol.</i> 75(4):389-396 (1997).
C64	Gallimore, A., <i>et al.</i> , "Early Suppression of SIV Replication By CD8 ⁺ <i>nef</i> -specific Cytotoxic T Cells in Vaccinated Macaques," <i>Nature Med.</i> 1(11):1167-1173 (1995).

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C65	Greenspan, N.S. and DiCera, E., "Defining Epitopes: It's not as Easy as it Seems," <i>Nature Biotechnol.</i> 17:936-937 (1999).
C66	Grosenbach, D.W., <i>et al.</i> , "Synergy of Vaccine Strategies to Amplify Antigen-specific Immune Responses and Antitumor Effects," <i>Cancer Res.</i> 61:4497-4505 (2001).
C67	Hanke, T., <i>et al.</i> , "DNA Multi-CTL Epitope Vaccines for HIV and <i>Plasmodium falciparum</i> : Immunogenicity in Mice," <i>Vaccine</i> 16(4):426-435 (1998).
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C69	Hill, A.V.S., <i>et al.</i> , "Common West African HLA Antigens are Associated with Protection from Severe Malaria," <i>Nature</i> 352(6336):595-600 (1991).
C70	Hill, A.V.S., <i>et al.</i> , "DNA-Based Vaccines for Malaria: a Heterologous Prime-Boost Immunisation Strategy," <i>Dev. Biol.</i> 104:171-179 (2000).
C71	Hirsch, V.M., <i>et al.</i> , "Patterns of Viral Replication Correlate with Outcome in Simian Immunodeficiency Virus (SIV)-Infected Macaques: Effect of Prior Immunization with a Trivalent SIV Vaccine in Modified Vaccinia Virus Ankara," <i>J. Virol.</i> 70(6):3741-3752 (1996).
C72	HIV CTL Epitopes Table 2: p24. [online], December 1996. Retrieved from the Internet <URL:http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/p24.pdf>.
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C74	HIV CTL Epitopes Table 4: Pol [online], December 1997. Retrieved from the Internet <URL:http://hiv-web.lanl.gov/content/hiv-db/immunology/PDF/1997/CTL/tables/pol.pdf>.
C75	HIV CTL Epitopes Table 6: gp120. [online], December 1996. Retrieved from the Internet <URL:http://hiv-web-lanl.gov/content/immunology/pdf/1996/CTL/TABLES/gp120.pdf>.
C76	HIV CTL Epitopes Table 7: gp41. [online], December 1996. Retrieved from the Internet <URL:http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/gp41.pdf>.

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C77	HIV CTL Epitopes Table 8: Nef. [online], December 1996. Retrieved from the Internet <URL:http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/nef.pdf>.	
C78	Holder, A., <i>et al.</i> , "Falciparum Malaria MSP1 Workshop: Progress toward MSP1 Vaccine Development and Testing," <i>Malaria Vaccine Initiative at PATH</i> : 1-30 (2000).	
C79	Huygen, K., <i>et al.</i> , "Immunogenicity and Protective Efficacy of a Tuberculosis DNA Vaccine," <i>Nature Med.</i> 2(8): 893-898 (1996).	
C80	Irvine, K.R., <i>et al.</i> , "Route of Immunization and the Therapeutic Impact of Recombinant Anticancer Vaccines," <i>J. Natl. Cancer Inst.</i> 89(5):390-392 (1997).	
C81	Irvine, K., <i>et al.</i> , "Comparison of a CEA-Recombinant Vaccinia Virus, Purified CEA, and an Anti-Idiotypic Antibody Bearing the Image of a CEA Epitope in the Treatment and Prevention of CEA-Expressing Tumors," <i>Vaccine Res.</i> 2(2):79-94 (1993).	
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C83	Kent, S.J., <i>et al.</i> , "A Recombinant Avipoxvirus HIV-1 Vaccine Expressing Interferon-gamma is Safe and Immunogenic in Macaques," <i>Vaccine</i> 18:2250-2256 (2000).	
C84	Kent, S.J., <i>et al.</i> , "Analysis of Cytotoxic T Lymphocyte Responses to SIV Proteins in SIV-Infected Macaques Using Antigen-Specific Stimulation with Recombinant Vaccinia and Fowl Poxviruses," <i>AIDS Res. Hum. Retroviruses</i> 10(5):551-560 (1994).	
C85	Laidlaw, S.M. and Skinner, M.A., "Comparison of the Genome Sequence of FP9, an attenuated, tissue culture-adapted European strain of <i>Fowlpox virus</i> , with those of virulent American and European viruses," <i>J. Gen. Virol.</i> 85:305-322 (2004).	
C86	Laidlaw, S.M., <i>et al.</i> , "Fowlpox Virus Encodes Nonessential Homologs of Cellular Alpha-SNAP, PC-1, and an Orphan Human Homolog of a Secreted Nematode Protein," <i>J. Virol.</i> 72(8):6742-6751 (1998).	

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C87	Lalvani, A., <i>et al.</i> , "An HLA-based Approach to the Design of a CTL-Inducing Vaccine Against <i>Plasmodium falciparum</i> ," <i>Res. Immunology</i> 145(6):461-468 (1994).
C88	Lanar, D.E., <i>et al.</i> , "Attenuated Vaccinia Virus-Circumsporozoite Protein Recombinants Confer Protection against Rodent Malaria," <i>Infect. Immun.</i> 64(5):1666-1671 (1996).
C89	Layton, G.T., <i>et al.</i> , "Induction of Single and Dual Cytotoxic T-Lymphocyte Responses to Viral Proteins in Mice Using Recombinant Hybrid Ty-Virus-Like Particles," <i>Immunology</i> 87(2):171-178 (1996).
C90	Leong, K.H., <i>et al.</i> , "Selective Induction of Immune Responses by Cytokines Coexpressed in Recombinant Fowlpox Virus," <i>J. Virol.</i> 68(12):8125-8130 (1994).
C91	Leong, K.H., <i>et al.</i> , "Generation of Enhanced Immune Responses by Consecutive Immunization with DNA and Recombinant Fowl Pox Vectors," <i>Vaccines</i> 95:327-331 (1995).
C92	Limbach, K.J. and Paoletti, E., "Non-Replicating Expression Vectors: Application in Vaccine Development and Gene Therapy," <i>Epidemiol. Infect.</i> 116:241-256 (1996).
C93	Mahnel, <i>et al.</i> , "Experiences with Immunization Against Orthopox Viruses of Humans and Animals Using Vaccine Strain MVA," <i>Berliner Und Munchener Tierarztliche Wochenschrift</i> 107(8):253-256 (1994) ABSTRACT ONLY
C94	Mayr, A. and Malicki, K., "Attenuierung von virulentem Hühnerpockenvirus in Zellkulturen und Eigenschaften des attenuierten Virus," <i>Zbl. Vet. Med. B</i> B13:1-13 (1966).
C95	Meyer, H., <i>et al.</i> , "Mapping of Deletions in the Genome of the Highly Attenuated Vaccinia Virus MVA and their Influence on Virulence," <i>J. Gen. Virol.</i> 72:1031-1038 (1991).
C96	Moorthy, V.S., <i>et al.</i> , "Safety of DNA and Modified Vaccina Virus Ankara Vaccines Against Liver-Stage <i>P. falciparum</i> Malaria in Non-Immune Volunteers," <i>Vaccine</i> 21(17-18):1995-2002 (2003).
C97	Moorthy, V. and Hill, A.V.S., "Malaria Vaccines," <i>Br. Med. Bull.</i> 62:59-72 (2002).

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	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645	

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